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09/787,498	03/16/2001	A. Bruno Frazier	6300.96.1	3953

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EXAMINER

ODLAND, KATHRYN P

ART UNIT PAPER NUMBER

3743

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/787,498	Applicant(s) FRAZIER ET AL.	
	Examiner Kathryn Odland	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 30-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 30-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated September 17, 2004. Claims 1-28 and 30-54 are under consideration.

Response to Arguments

1. Applicant's arguments filed September 17, 2004 have been fully considered but they are not persuasive.

Applicant has amended claim 1 to include the limitation, "wherein the microneedles are located on the major surface of the substrate such that the microneedles extend in a direction substantially parallel to the major surface." Applicant argues, "In contrast Gerstel discloses that projections 12 extend outward from the major surface so that the projections are perpendicular to the major surface, as shown in Figures 1-4." However, the examiner respectfully disagrees. In a reasonably broad interpretation, the substrate is shown at the arrow (10) in figure 1. The elements 16 and 14 are of unitary structure. Thus, element 16 is considered a part of the major substrate. Therefore, the needles (12) are located on the portion 14 of the unitary substrate and the microneedles extend in a direction parallel to portion 16 of the major substrate. Applicant has failed to define structural limitations that define over the prior art rejection.

Applicant has also amended claim 22 to include the limitations, "at least one first structural support member that interconnects the microneedles adjacent the proximal end of the microneedles" and "at least one second structural support member that

interconnects the microneedles adjacent the distal end of the microneedles." Applicant argues, "There is no teaching or suggestion in Gerstel of a 'second structural support member that interconnects the microneedles adjacent the distal end of the microneedles." However, the examiner respectfully disagrees, in column 6, lines 55-65 Gerstel discloses a cover 33 that can be considered "at least one second structural support member that interconnects the microneedles adjacent the distal end of the microneedles."

Applicant has amended claim 43 to include the limitation that the microneedle device has a "single" needle. However, applicant discloses both multiple and single needle embodiments and does not disclose the criticality of a single needle embodiment. Thus, it can be considered an equivalent to the multiple needle embodiments.

Regarding claim 51, applicant has amended to include the limitation, "wherein the microneedles are formed on the major surface of the substrate such that the microneedles extend in a direction substantially parallel to the major surface." However, this is an extraordinarily broad limitation and given a reasonably broad interpretation that disclosed by Miura et al. meets the limitation. Miura et al. disclose a substrate³¹ that has two dimensions. There is a length and thickness. Thus, in a reasonably broad interpretation the microneedles extend parallel to the thickness component of the major surface. Applicant appears to be arguing an extremely narrow interpretation of the limitation.

Applicant has failed to define structural limitations to define over the prior art of record. Thus, the rejection is reiterated below and made final.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 8-11, 13-18, 20-28, and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerstel et al. in US Patent No. 3,964,482.

Regarding claim 1, Gerstel et al. disclose a microneedle array (10) device having a substrate (such as 14) having a substantially planar major surface and a plurality of hollow non-silicon microneedles (12) on the major surface of the substrate, as recited in columns 4-6 and seen in figure 1-6, with emphasis on column 4, lines 23-35, column 6, lines 30-40 and column 8. Each of the microneedles has a microchannel (11) therethrough that provides communication between at least one input port at a proximal end of each of the microneedles and at least one output port at an opposite distal end that extends beyond an edge of the substrate, as recited in columns 4-6. In a reasonably broad interpretation, the substrate is shown at the arrow (10) in figure 1. The elements 16 and 14 are of unitary structure. Thus, element 16 is considered a part of the major substrate. Therefore, the needles (12) are located on the portion 14 of the unitary substrate and the microneedles extend in a direction parallel to portion 16 of the major substrate. Applicant has failed to define structural limitations that define over the prior art rejection.

Regarding claims 2 and 23, Gerstel et al. disclose that as applied to claims 1 and 22, as well as, microneedles each having a bottom wall, two side walls, and a top wall that define a microchannel, necessary of a hollow structure. Given a reasonably broad interpretation, even a tube can be considered having walls.

Regarding claim 3, Gerstel et al. disclose that as applied to claim 2, as well as, a bottom wall is formed at least partially on top of the major surface of the substrate and the side walls and top wall are formed around a removable molding material, as recited in column 8 and column 9.

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Regarding claims 4 and 24, Gerstel et al. disclose that as applied to claims 1 and 22, as well as, microneedles that are in a two dimensional array, as seen in figures 1-4.

Regarding claims 5 and 25, Gerstel et al. disclose that as applied to claims 2 and 22, as well as, microneedles that are in a three dimensional array, as seen in figure 2, where the device spans in 3 dimensions.

Regarding claim 8, Gerstel et al. disclose that as applied to claim 1, as well as, microneedles that are aligned substantially parallel to each other on the substrate, as seen in figures 1-4.

Regarding claim 9, Gerstel et al. disclose that as applied to claim 1, as well as, a distal end of each microneedle that extends beyond the edge of the substrate a distance from about 10 μm to about 100 μm , as recited in column 7, lines 60-67.

Regarding claim 10, Gerstel et al. disclose that as applied to claim 1, as well as, microneedles having a cross-sectional area in the range from about 25 μm^2 to about 5000 μm^2 , as recited in column 7, lines 52-55. A 15-40 gauge size falls within the range.

Regarding claim 11, Gerstel et al. disclose that as applied to claim 1, as well as, a length of each microneedle that is from about 0.05 μm to about 5 mm , and the width of each microneedle is from about 0.05 μm to about 1 mm , as recited in column 7, lines 40-67.

Regarding claim 13, Gerstel et al. disclose that as applied to claim 1, as well as, a substrate of a material selected from the group consisting of glass, semiconductor materials, metals, ceramics, plastics, and composites or combinations thereof, as recited in column 8, lines 30-60.

Regarding claims 14 and 26, Gerstel et al. disclose that as applied to claims 1 and 22, as well as, microneedles of a material selected from the group consisting of metals, plastics, ceramics, glass, carbon black, and composites or combinations thereof, as recited in column 8, lines 30-60.

Regarding claims 15 and 27, Gerstel et al. disclose that as applied to claims 1 and 22, as well as, microneedles comprise a metal material selected from the group consisting of nickel, copper, gold, palladium, titanium, chromium, and alloys or combinations thereof, as recited in column 8, lines 30-60.

Regarding claim 16, Gerstel et al. disclose that as applied to claim 1, as well as, microneedles that can withstand flow rates of up to about 1.5 cc/sec .

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Regarding claims 17 and 28, Gerstel et al. disclose that as applied to claims 1 and 22, as well as, a coupling channel member (16) that provides fluid communication between the microneedles.

Regarding claim 18, Gerstel et al. disclose that as applied to claim 17, as well as, a coupling channel member is composed of the same material as the microneedles.

Regarding claims 20 and 31, Gerstel et al. disclose that as applied to claims 1 and 22, as well as, microneedles have a plurality of input ports, as seen in figures 1-4.

Regarding claims 21 and 32, Gerstel et al. disclose that as applied to claims 1 and 22, as well as, microneedles that have a plurality of output ports.

Regarding claim 22, Gerstel et al. disclose a microneedle array device (10) having a plurality of hollow non-silicon microneedles (12) having a microchannel (such as 11) therethrough that provides communication between at least one input port at a proximal end of each of the microneedles and at least one output port at an opposite distal end; and at least one structural support member (14) that interconnects the microneedles, as recited in column 4-8 and seen in figures 1-4. In column 6, lines 55-65, Gerstel discloses a cover 33 that can be considered "at least one second structural support member that interconnects the microneedles adjacent the distal end of the microneedles."

Regarding claim 30, Gerstel et al. disclose that as applied to claim 22, as well as, at least one structural support member (14) that precisely controls penetration depth of the microneedles, as seen in figures 1-4. Given the structure, the needles cannot penetrate further than the member (14) permits.

4. Claims 51-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Miura et al. in US Patent No. 4,728,392.

Regarding claim 51, Miura et al. disclose a method via providing a substrate (31) with a substantially planar major surface; depositing a metal material (32) on a major surface to form one or more bottom walls for one or more microneedles/nozzles, as recited in column 6, lines 35-65; coating a top surface of the one or more bottom walls with a photoresist layer (33) to a height corresponding to a selected inner height of a microchannel for the one or more microneedles; depositing a metal material to form side walls and a top wall upon the one or more bottom walls and around the photoresist layer; and removing the photoresist layer from the microchannel of the one or microneedles/nozzles, as

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recited in column 6, lines 35-65. Miura et al. disclose a substrate 31 that has two dimensions. There is a length and thickness. Thus, in a reasonably broad interpretation the microneedles extend parallel to the thickness component of the major surface.

Regarding claim 52, Miura et al. disclose that as applied to claim 51, as well as, metal material that is deposited by an electroplating process, as recited in column 6, lines 45-47.

Regarding claim 53, Miura et al. disclose that as applied to claim 51, as well as, a metal material that is selected from the group consisting of palladium, titanium, chromium, nickel, gold, copper, and alloys thereof, as recited in column 6, lines 43-50.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 12, 19, 33-50 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel et al. in US Patent No. 3,964,482.

Regarding claim 12, Gerstel et al. disclose that as applied to claim 1. However, Gerstel et al. do not explicitly recite a center-to-center spacing between individual microneedles that is from about 50 um to about 200 um. On the other hand, it would be obvious to one with ordinary skill in the art to modify the invention to have the needles be spaced as claimed for the purpose of maximizing the amount of needles in a given space.

Regarding claims 19 and 54, Gerstel et al. disclose that as applied to claims 1 and 22. However, Gerstel et al. do not explicitly recite a pair of/plurality of structural support members that mechanically interconnect the microneedles. On the other hand, it would be obvious to one with ordinary skill in the art to modify the invention of Gerstel et al. to include interconnects for the purpose of more precisely controlling penetration depth of the microneedles, as dependent upon the application.

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Regarding claim 33, Gerstel et al. disclose a microneedle device (10) having a substrate (14) having a substantially planar surface; and hollow non-silicon microneedles (12) on the planar surface of the substrate, the microneedle having at least one microchannel (11) therethrough that provides communication between at least one input port at a proximal end of the microneedle and at least one output port at an opposite distal end that extends beyond an edge of the substrate. However, Gerstel et al. do not recite only one single microneedle. However, given applicant discloses the embodiments of both multiple and single hollow microneedles, they can be considered equivalents. Thus, it would be obvious to one with ordinary skill in the art to have single or multiple microneedles depending on the application.

Regarding claims 34-37 and 41, Gerstel et al. as modified discloses that as applied to claim 33. See corresponding rejections for claims 9, 10, 13, 15 and 30.

Regarding claims 38-40, Gerstel et al. as modified discloses that as applied to claim 33. Further a microneedle that has a proximal end has a having a plurality of input ports, a plurality of output ports and a plurality of microchannels would further be obvious to one with ordinary skill in the art.

Regarding claim 42, Gerstel et al. as modified discloses that as applied to claim 41, and a structural support that is adapted to mechanically fix the microneedle device to a surface that is penetrated by the microneedle is also within the scope of the invention.

Regarding claim 43, Gerstel et al. disclose a microneedle device (10) having a hollow elongated shaft (12) of a non-silicon material, the shaft defining at least one microchannel (11) therethrough and having a proximal end and a distal end and at least one input port at the proximal end of the shaft and at least one output port at the distal end, the microchannel providing communication between the at least one input port and the at least one output port, as recited in column 4-8 and seen in figures 1-4. However, Gerstel et al. do not recite only one single microneedle. However, given applicant discloses the embodiments of both multiple and single hollow microneedles, they can be considered equivalents. Thus, it would be obvious to one with ordinary skill in the art to have single or multiple microneedles depending on the application.

Regarding claim 44, Gerstel et al. as modified disclose that as applied to claim 43, as well as, microneedles having a cross-sectional area in the range from about 25 um^2 to about 5000 um^2 , as recited in column 7, lines 52-55. A 15-40 gauge size falls within the range.

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Regarding claims 45, Gerstel et al. disclose that as applied to claim 43, as well as, microneedles comprise a metal material selected from the group consisting of nickel, copper, gold, palladium, titanium, chromium, and alloys or combinations thereof, as recited in column 8, lines 30-60.

Regarding claim 46, Gerstel et al. disclose that as applied to claim 43, as well as, microneedles have a plurality of input ports, as seen in figures 1-4.

Regarding claim 47, Gerstel et al. disclose that as applied to claim 43, as well as, microneedles that have a plurality of output ports.

Regarding claim 48, Gerstel et al. disclose that as applied to claim 43, as well as, a plurality of microchannels (11), as seen in figures 1-4.

Regarding claim 49, Gerstel et al. disclose that as applied to claim 43, as well as, at least one structural support member (14) that precisely controls penetration depth of the microneedles, as seen in figures 1-4. Given the structure, the needles cannot penetrate further than the member (14) permits.

Regarding claim 50, Gerstel et al. disclose that as applied to claim 49, as well as, a structural support that is adapted to mechanically fix the microneedle device to the surface that is penetrated by the elongated shaft, given the structure.

7. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel et al. in US Patent No. 3,964,482 in view of Ozbay et al. in US Patent No. 5,406,573.

Regarding claim 6, Gerstel et al. disclose that as applied to claim 5. However, Gerstel et al. do not recite a three dimensional array having a plurality of two-dimensional arrays with spacers therebetween. On the other hand, Ozbay et al. teach arrays that are located on a major surface of a substrate, as recited in columns 12-19 and seen in figure 1. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Gerstel et al. to include a three dimensional array having a plurality of two-dimensional arrays with spacers in-between, as taught by Ozbay et al. for the purpose of ease of manufacture and transportation.

Regarding claim 7, Gerstel et al. as modified by Ozbay et al. disclose that as applied to claim 6. Further, it would be obvious to one with ordinary skill for the modification to have the three dimensional array bonded together by a material

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selected from the group consisting of molding materials, polymeric adhesives, and combinations thereof.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 51-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,876,582. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely a broader recitation of the same subject matter.

10. Claims 1-28 and 30-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 and 18-24 of U.S. Patent No. 5,871,158. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely a broader recitation of the same subject matter.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

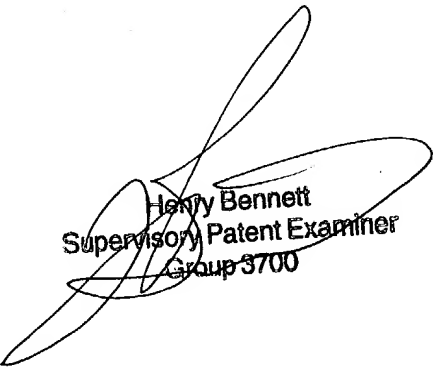
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (571) 272-4801. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



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